

*PICOTS FRAMEWORK*

# COMPARATOR

PCORI-izing your Study Design

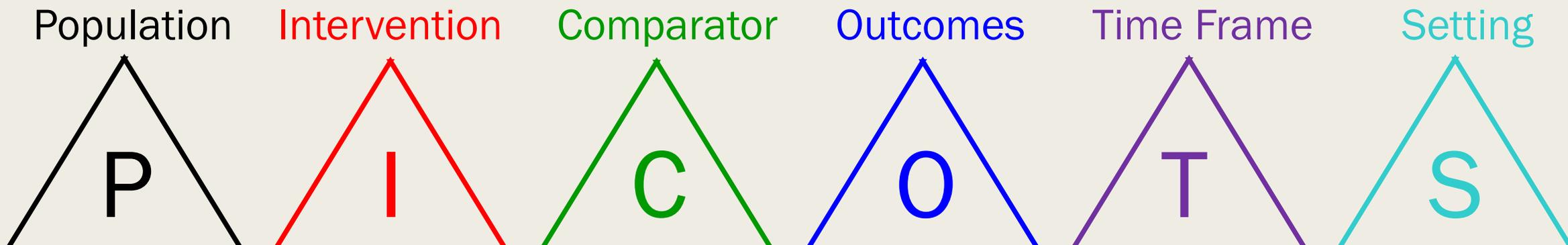


# PICOTS Framework and CER

- Previous presentation defined overall PICOTS Framework, Population, and Intervention

## Example:

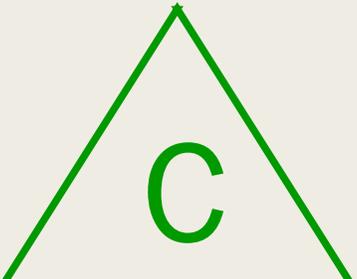
Is **robotic assistance knee surgery** more effective than **conventional knee surgery** in achieving **mobility** for middle age men in **rural communities** during the **first six months** following surgery?



# Objectives

- In-depth look at “Comparator” aspect of the PICOTS framework
- Describing comparators in your PCORI applications

Comparator



C

# PCORI Definitions of Comparators

- PCORI Methodology Standards: Formulating Research Questions (RQ-5)

When evaluating an intervention, the comparator treatment(s) must be chosen to enable accurate evaluation of effectiveness or safety compared to other viable options for similar patients. Researchers should make explicit what the comparators are and how they were selected, focusing on **clearly describing how the chosen comparator(s) define the causal question, reduce the potential for biases, and allow direct comparisons.**

Generally, non-use (or no specific treatment) comparator groups should be avoided unless no specific treatment is a likely option in standard care.

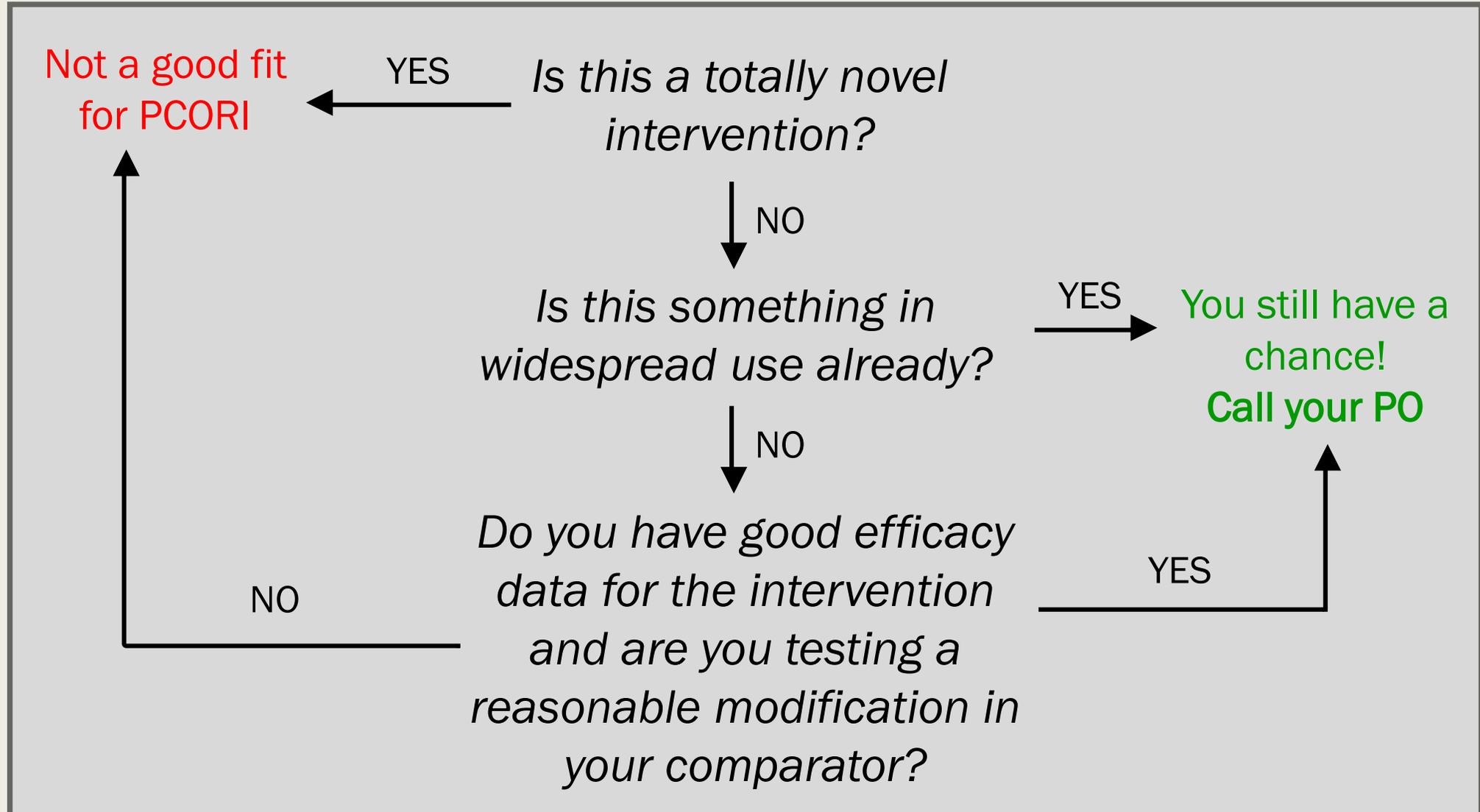
# A “Good” Comparator Needs...

## DETAILED BACKGROUND

- Efficacy: How well does the comparator work in clinical trials or lab studies?
- Effectiveness: How well does the comparator work in real-life practice?
- Wide use: How often is this comparator implemented in the real world?

# Grey areas

## What if I don't really have good efficacy data for my comparator?



# A “Good” Comparator Needs...

## **SPECIFIC AND DETAILED METHODOLOGY**

- Definition: Need to be able to clearly define the comparator, readily understandable to reviewer
- Implementation: Need to describe how this comparator is readily implemented in real world settings, specifically for your defined population
- Measurement: Need to describe how exactly you are measuring all aspects of the comparator

# Grey areas

Usual Care/Standard of Care?

NO



Not a good  
fit for PCORI

*Can you demonstrate  
measurability?*

YES



You still have a  
chance!  
Call your PO

# Grey areas

Not a good  
fit for PCORI

NO

*Is there a compelling reason  
why other available  
comparators cannot be used?*

YES

You still have a  
chance!  
Call your PO

YES

*Are >1 active comparators  
options available?*

NO

Use of Placebo?

# A “Good” Comparator Needs...

## SIGNIFICANCE

- Intent: How does comparing your chosen comparators address critical evidence gaps?
- Patient Participation: What was the process that led to these specific comparators being chosen by your patient partners? Explain why these comparators are meaningful to patients
- Potential for Dissemination: Are these comparators available now? Can these results be adopted nationwide?

# Funded Examples of Comparators

- *Straight forward:*

## Warfarin versus Direct Oral Anticoagulants for Secondary Prevention of Recurrent Venous Thromboembolism: A Randomized Comparative Effectiveness Trial

We are proposing a research study that will compare three of these medicines in patients with a DVT who need to take anticoagulant therapy long-term: warfarin (Coumadin), rivaroxaban (Xarelto), and apixaban (Eliquis). Warfarin has been around the longest, and requires having regular blood checks to make sure it is in the right range. Rivaroxaban and apixaban are newer and do not require any laboratory testing. Warfarin also interacts with many foods, which is not a problem with rivaroxaban and apixaban. Our research study will determine whether the new medications are as good as warfarin and whether they have fewer problems with bleeding complications, which can occur with any anticoagulant.

# Funded Examples of Comparators

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We are proposing a research study that will compare three of these medicines in patients with a DVT or PE who need to take anticoagulant therapy long-term: **warfarin (Coumadin)**, **rivaroxaban (Xarelto)**, and **apixaban (Eliquis)**. Warfarin has been around the longest, and requires having regular blood checks to make sure it is in the right range. Rivaroxaban and apixaban are newer and do not require any laboratory testing. Warfarin also interacts with many foods, which is not a problem with rivaroxaban and apixaban. Our research study will determine whether the new medications are as good as warfarin and whether they have fewer problems with bleeding complications, which can occur with any anticoagulant.

**Comparators**

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Comparators

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(Efficacy/Effectiveness)

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Comparators

Background

(Efficacy/Effectiveness)

Significance

# Funded Examples of Comparators

- Persuasive: What constitutes efficacy

## Comparing the Effectiveness of Clinicians and Paraprofessionals to Reduce Disparities in Perinatal Depression

Over the past five years, researchers and community stakeholders have worked closely to conduct research that has shown that one intervention—the Mothers and Babies Course (MB)—is effective in preventing new cases of major depression and reducing depressive symptoms when led by mental health clinicians. In this PCORI project, we will determine whether paraprofessional home visitors can achieve similar reductions in depressive symptoms and prevention of new cases of major depression when delivering MB as mental health clinicians do. We are also interested in other patient-centered outcomes, such as quality of life, parenting practices, engagement in pleasant activities, and relationship with one's partner.

# Funded Examples of Comparators

- Persuasive: What constitutes efficacy

Comparing the Effectiveness of **Clinicians** and **Paraprofessionals** to Reduce Disparities in Perinatal Depression

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**Background**

(Efficacy/Effectiveness)

**Comparators**

**Significance**

**KEY:**

**Intervention itself was proven to be efficacious!**

# Funded Examples of Comparators

- Persuasive: Use of usual care

## Engaging Patients and Providers in Collaborative Communication on HPV Vaccination (EPPIC-HPV)

This project will employ a developed and efficacious web-based intervention on HPV messaging, GoHealthyGirls.org, as a way to improve knowledge, communication, and shared decision making about HPV vaccination between 11- to 13-year-old girls, their parents, and clinicians. A clinic-based comparative effectiveness randomized trial will be used to examine the impact of the GoHealthyGirls website on vaccine-related outcomes and vaccine uptake. Pediatric clinics within New Mexico will be randomly assigned to either the usual care clinic-based communication about HPV vaccination or to usual care plus web-based dissemination...An effective web-based resource should increase parents' knowledge, intentions, and motivations to vaccinate, enhance shared decision making for HPV vaccination, and increase HPV vaccination rates.

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**Background**

(Efficacy/Effectiveness)

**Comparators**

**Significance**

# Conclusions

- PCORI applications expect comparators to be described in a PCORI-esque way
  - Detailed Background
  - Specific and Detailed Methodology
  - Significance
- Activate your partnership in order to best describe the rationale behind your chosen comparators
- Explore the grey area! Contact [sciencequestions@pcori.org](mailto:sciencequestions@pcori.org)

***BE PERSUASIVE!***

# Questions or Comments?

*Thanks for watching!*

